

K080302

Summary of Safety and Effectiveness
for the
Cayman Buttress Plate System

MAR 24 2008

This safety and effectiveness summary for the Cayman Buttress Plate System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :

K2M, Inc.
751 Miller Drive SE,
Suite F1
Leesburg, VA 20175

Contact Person :

Richard W. Woods
K2M, LLC
751 Miller Drive SE, Suite F1
Leesburg, VA 20175
Telephone: 703-777-3155

Date Prepared:

2. Tradename:

Cayman Buttress Plate System

Common Name:

Buttress Plate

Classification Name:

Spinal intervertebral body fixation orthosis (21 CFR 888.3060)

3. Predicate or legally marketed devices which are substantially equivalent :

- Seaspine Anterior Lumbar Buttress System
- BowTi Anterior Staple System
- Synthes Titanium Locking Plate System
- Altiva Buttress Plating System
- Medtronic Sofamor Danek Bone Graft Washer

4. Description of the device:

The Cayman Buttress Plate System are non-load bearing devices, each consisting of a screw and plate of various sizes and screw for attachment to the vertebral body in the anterior lumbar spine.

Materials: The devices are manufactured from CP Titanium and Ti6Al4V per ASTM and ISO standards.

Function: The plates are designed to be used in spinal fusion procedures to provide stabilization and buttressing of tissue in the intervertebral space.

5. Intended Use:

The Cayman Buttress Plate System is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

The Cayman Buttress Plate System is considered substantially equivalent to other legally marketed devices. They are similar in design, material, and indications for use and are expected to be equivalent in safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 24 2008

K2M, Inc.
% Mr. Richard W. Woods
751 Miller Drive SE, Suite F-1
Leesburg, VA 20175

Re: K080302
Trade/Device Name: Cayman Buttress Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: Feb 04, 2008
Received: Feb 07, 2008

Dear Mr. Woods:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Richard W. Woods

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Cayman Buttress Plate System

Indications for Use:

The Cayman Buttress Plate System is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications.

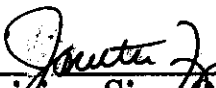
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS-LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



j1 (Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K080302